VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 09/11/07

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Kathleen Boland, Pharm.D.
Rich Harvie, R.Ph.
Norman Ward, M.D.
Cheryl Gibson, M.D.
Lynne Vezina, R.Ph.
Frank Landry, M.D.
Virginia Hood, M.D.

Staff:

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
Scott Strenio, M.D., OVHA
Nancy Miner, (MHP)
Erin Reisfeld, M.D., OVHA
Clark Eaton, OVHA

Guests:

Adam Jones, Abbott Diabetes Care
Andrea Hayes, Sanofi-Aventis
Angela Andreoli-Gallagher, IPS
Art McNulty, Forest
Bob Clark, Novartis
Bob Meany, Takeda
Carl Marchand, AstraZeneca
Carl Pepe, GSK
Ellen K Flatley, GSK
Jim Kelley, AstraZeneca
Jolie-Beth Bonue, TAP
Joseph Winalski, Boehringer-Ingelheim
Keith White, Genentech
Kevin Pellon, Wyeth
Larry Forti, Pfizer
Lisa Wentworth, Merck-Schering-Plough
Lyndon Braun, Santarus
Mark Kaplan, Abbott
Michael Nelson, Novartis
Natalia Raphael, Alexion
Paul Amato, GSK
Rozina Khanna, GSK
Scott Mosher, GSK
Tom Martin, Boehringer-Ingelheim
Tony McLeod, Alexion
Tracy Wall, Merck
Ward Bennett, J&J

Michael Scovner, M.D., Chair, called the meeting to order at 7:08 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The June 2007 meeting minutes were accepted as printed without amendment.

Public Comment: No public comment.

3. Medical Director Update: *Scott Strenio, M.D. – Medical Director, OVHA*

- Buprenorphine Program: 35 providers (taking care of 300 patients) have been enrolled in the program to date. The incentives being provided to physicians appear to be attracting more providers.
- Dr. Strenio Resigns: Dr. Strenio announced that he would be leaving OVHA to take the position of medical director at APS Healthcare. Dr. Erin Reisfeld will be taking over the position of medical director at OVHA.

4. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- Specialty Pharmacy Requests for Proposals: In an effort to address chronic conditions and their therapies, some of which may be expensive, a specialty pharmacy request for proposal was released, with the initial drug being targeted being Synagis®.
- Tamper Resistant Prescription Pads: This requirement was part of a Federal bill signed in May and CMS has only recently released guidance on this issue. The expectation is that one of three requirements be in place by October 1st. The pharmacies will be responsible for ensuring that Medicaid prescriptions are written on tamper resistant prescription pads. A prescriber and pharmacy alert have been sent out by OVHA.
- SSDC Supplemental Rebate Procurement Update: The SSDC now includes the state of Utah. The annual meeting is on September 17th and 18th to review offers.
- Vaccine Availability and the Vermont Department of Health: The Health Department has an abundance of vaccines for certain age groups. It is relatively easy for providers to participate in the vaccines for children program. Vaccines provided free of charge for children will now reject at the pharmacy for Medicaid recipients with messaging directing that the vaccine is provided by the Health Department. OVHA will be distributing information to pharmacies to educate them about this program.
- Drug Use Patient Profiles: OVHA has proposed providing drug use histories/profiles of Medicaid patients to prescribers and pharmacies. This would be a web based tool and is in the early planning stages.

5. Follow-up items from Previous Meeting: *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

- Methadone
  A prior authorization form was developed for methadone 40 mg tablets. It is a combination prior authorization request form and educational resource.

Public Comment: No public comment.

Board Decision: None needed.

6. Clinical Update: New Drug Reviews: *Diane Neal, R.Ph.(MHP)*

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Tekturna® (aliskiren) – Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the patient has a diagnosis of hypertension and the patient has a documented side effect, allergy, or treatment failure to an ARB (which would mean that there had also been a side effect, allergy, or treatment failure to an ACE inhibitor). A quantity limit of 1 tablet per day was recommended.

Public Comment: *Dr. Martin LeWinter, M.D.* – Submitted an email addressing the role of Tekturna® in the treatment of hypertension.
Bob Clark, Novartis – Asked for clarification regarding the step edit and whether this would be automated.

Board Decision: The Board approved the MHP recommendations as described but requested that the PA approval be lifetime.

- Coreg CR® (carvedilol phosphate extended release) – Not recommended for addition to the PDL. Recommendations for criteria for coverage of Coreg CR® for heart failure would include that the patient had been started and stabilized on carvedilol ER or the patient has a documented side effect, allergy, or treatment failure to metoprolol SR or bisoprolol and the patient has been unable to be compliant with twice daily dosing of carvedilol IR. Recommendations for criteria for coverage of Coreg CR® for use in hypertension would include that the patient has been started and stabilized on cervedilol ER or the patient has a documented side effect, allergy, or treatment failure to 3(three) of the PDL preferred antihypertensive beta-blockers. The recommended quantity limit is 1 capsule per day for all strengths.

Public Comment: *Carl Pepe, GSK* – Commented on the competitive pricing of brand name Coreg®/Coreg CR®.
Rozina Khanna, GSK – Commented on the unique properties of Coreg CR® and that it may offer better tolerability and adherence than Coreg® IR.

Board Decision: The Board approved the MHP recommendations noted above with the requested addition of "unable to tolerate" carvedilol IR to the heart failure indication.

- Omnitrope® (somatotropin [rDNA origin]) – Recommended for addition to the PDL (preferred after clinical criteria are met). Criteria for coverage would be the same as for the other growth hormones.

Public Comment: *Bob Clark, Novartis* – Commented on his understanding of biosimilar products.

Board Decision: The Board approved the MHP recommendations noted above. The Board requested additional information on the general approval process for biosimilar products.

- Soliris® Injection (eculizumab) – Not recommended for addition to the PDL (require PA) to ensure correct billing and to alert OVHA that a patient has been diagnosed with this condition. Criteria for coverage would include diagnosis of paroxysmal nocturnal hemoglobinuria and the recommended quantity limit is 20 vials total with an initial approval duration of 3 months and a quantity limit of 6 vials per month. It was recommended that Soliris® also require PA if the claim is processed through the medical benefit.

Public Comment: *Natalia Raphael, Alexion* – Commented on the use of this drug and the role of stem cell transplant in this disease.
Tony McLeod, Alexion – Commented on the cost of this ultra orphan drug and the occasional need for every 12 day dosing as opposed to every 14 day dosing.

Board Decision: The Board approved the MHP recommendations noted above.

7. Review of Newly-Developed/Revised Clinical Coverage Criteria: *Diane Neal, R.Ph, (MHP)*

- Analgesics: Short Acting Narcotics and Stadol® Nasal Spray: (merging of categories)
  Two categories (Analgesics: Short Acting Narcotics and Stadol® Nasal Spray) were combined into one category. In addition, criteria for approval of Stadol® nasal spray were developed. Criteria for approval of Stadol® include that the member has had a documented side effect, allergy, treatment failure, or contraindication to codeine, hydrocodone, morphine and oxycodone (all 4 generic entities) as single or combination products or the member is unable to use tablet or liquid formulations and the quantity requested does not exceed 2 bottles/month.

Public Comment: No public comment.

Board Decision: The combined category with the presented clinical criteria for Stadol® was unanimously accepted.

- Anti-Anxiety: Anxiolytics:
  The table had never included alprazolam XR and clonazepam ODT as preferred though claims for these dosage forms currently process. The criteria for approval of non-preferred products was reworded to require a trial of an AB rated generic, if applicable.

Public Comment: No public comment.

Board Decision: The updated table and revised criteria were unanimously accepted.

- Anti-Emetics: NK1 Antagonists:
  The criteria were revised to accommodate multiple courses of chemotherapy or surgery per month that would require the quantity limits to be exceeded.

Public Comment: No public comment.

Board Decision: The clinical criteria were accepted unanimously.

- Anti-Hyperkinesis and Anti-Narcolepsy: (merging of categories)
  It was recommended that the anti-hyperkinesis and anti-narcolepsy (Zyrem®) categories be merged. The criteria for approval of Zyrem® were rewritten to be clearer. It should be noted that the length of authorization for mental health indications is duration of need while the length of authorization for other indications is 1 year.

Public Comment: No public comment.

Board Decision: The Board approved the merging of the categories and clinical criteria as recommended.

- Anti-Infectives: Antibiotics: Oxazolidinones:
  Criteria for the approval of Zyvox® were presented as there were no criteria in the past.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

- Chemical Dependency: Buprenorphine:
  Due to the departure of Dr. Strenio, discussion of the criteria will be deferred until next month so that it can be discussed with Dr. Reisfeld before presentation to the DUR Board.

- Glucocorticoids: Topical (Verdeso® (desonide 0.05% foam – abbreviated review)):
  Verdeso® was not recommended for addition to the PDL. Criteria for approval of Verdeso® are that the patient has a documented side effect, allergy, or treatment failure to at least two different preferred agents of similar potency. These criteria will be the common criteria for all non-preferred products. Additionally, if a product has an AB rated generic, one trial must be the generic. The table has been expanded to indicate strength when a drug appears in more than one potency category.

Public Comment: No public comment.

Board Decision: The clinical criteria were accepted as presented.

- Lipotropics: Miscellaneous/Combinations: **(Proposed implementation 1/1/08)**
  It was recommended that Zetia® therapy require a prior trial of a statin which would be handled through automated step therapy (180 day look back).

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted with the request that the length of authorization be changed to lifetime.

- Management of Mental Health Medications (updated language):
  The language was updated to reflect how mental health medications are currently handled (length of approval, etc.) and when any changes were implemented (previously the language reflected what was going to be done 1/1/06). It should be noted that approval for brand name products where a generic exists will lapse after one year. This language will be incorporated into all mental health categories.

Public Comment: No public comment.

Board Decision: The revised wording was unanimously accepted.

- Pulmonary: Systemic Glucocorticoids (dose packs):
  The criteria were reformatted into the current format style. Additionally, if a product has an AB rated generic, one trial must be the generic before the brand name non-preferred product can be approved. It was recommended that dose packs no longer require PA as they are no more expensive than tablets not in special packaging and it is often easier for the patient to be compliant with the specialized packaging.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

- Anti-Emetics: 5HT3 Antagonists:
  Criteria were proposed for non-preferred agents. Additionally, criteria to exceed quantity limits were proposed. The table was also reformatted to more clearly show preferred and non-preferred agents.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

- Anti-Infectives: Antibiotics: Macrolides:
  The criteria were reformatted into the standard format. Additionally, if a product has an AB rated generic, one drug trial must be the generic to allow approval of the branded product. Criteria for approval of azithromycin quantity limits greater than 5 days were also presented.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

- Anti-Infectives: Antibiotics: Penicillins (Oral):
  The criteria were simply reformatted to be in the standard format.

Public Comment: No public comment.

Board Decision: The reformatted clinical criteria were unanimously accepted.

- Anti-Infectives: Antibiotics: Quinolones:
  Deferred until next month as more time was needed to evaluate the current quantity limits.

- Anti-Infectives: Antivirals: Herpes:
  The criteria were simply reformatted to be in the standard format.

Public Comment: No public comment.

Board Decision: The reformatted clinical criteria were unanimously accepted.

- Anti-Migraine: Triptans:
  The criteria were simply reformatted to be in the standard format. The table was also reformatted to more clearly show preferred and non-preferred agents.

Public Comment: No public comment.

Board Decision: The reformatted clinical criteria were unanimously accepted.

8. New Drug Classes: *Diane Neal, R.Ph. (MHP)*

No new drug classes were presented at this meeting.

9. RetroDUR: *Diane Neal, R.Ph, (MHP)*

- Acetaminophen Daily Dose > 4 grams per Day
  A retrospective drug utilization review of claims was conducted to evaluate pharmacy claims for drugs with daily doses of greater than 4 grams per day of acetaminophen from January 25, 2007 to April 25, 2007. Claims for doses of exactly 4 grams of acetaminophen per day were not included in this analysis. There were 146 claims for 47 unique members that met the criteria. Agents most commonly dosed at greater than 4 g/day APAP were hydrocodone/APAP 5/500 (30%) and hydrocodone/APAP 7.5/750 (29%). Other claims were for hydrocodone/APAP 10/500 (13%), propoxyphene/APAP 100/650 (10%), oxycodone/APAP 10/650 (4%), hydrocodone/APAP 10/650 (3%), hydrocodone/APAP 10/660 (3%), oxycodone/APAP 5/500 (2%), and others (6%). No claims for

acetaminophen/codeine exceeding 4 g of APAP were identified during this time period. No physician was identified as repeatedly responsible for prescriptions with daily doses of > 4 g of APAP. It was recommended that claims for the top 5 drugs identified in this analysis reject for acetaminophen doses exceeding 4 grams/day. Some alternative drugs for the top five most commonly prescribed APAP-containing products that exceeded a daily dose of 4 g are listed in an attached table. The clinical call center will have this table to help pharmacies/physicians choose alternative products. It was recommended that patient specific mailings be sent to prescribers with the attached table of suggested alternatives. It was also recommended that a repeat retrospective drug utilization review be performed in six months to determine the need for further coding changes.

Public Comment: No public comment.

Board Decision: The recommended coding changes were unanimously accepted.

- Zetia® Use as Monotherapy
  Pharmacy claims for ezetimibe from March 1, 2007 to June 30, 2007 were reviewed to identify the percentage of patients who were receiving ezetimibe monotherapy, combination therapy of ezetimibe plus a statin, and combination therapy of ezetimibe plus another lipid-lowering agent. Of the patients who were receiving ezetimibe monotherapy during this time period, a look back of 150 days from the first ezetimibe claim was performed to determine if the patient had a trial of a statin (lovastatin, pravastatin, simvastatin, fluvastatin, atorvastatin, rosuvastatin, or ezetimibe/simvastatin) prior to ezetimibe therapy. During this four month time period, 259 patients were identified as having filled one or more pharmacy claims for ezetimibe. Of these patients, 56% (145 patients) were receiving concurrent statin therapy, 35% (91 patients) were using ezetimibe monotherapy, 7% (18 patients) were receiving concurrent fibrate therapy, and 2% (5 patients) were receiving concurrent bile acid sequestrant therapy. Of the patients who were not receiving concurrent statin therapy, only 26% (30 out of 114 patients) had previous trials of statins. To encourage the appropriate prescribing of Zetia® and ensure that it is used in combination with a statin or after intolerance to a statin, revised clinical criteria for the use of the Zetia® were proposed (see above: Lipotropics: Miscellaneous/Combinations).

Public Comment: No public comment.

Board Decision: The recommended coding changes were unanimously accepted.

- Asthma Medication Therapy
  New national guidelines have recently been released by the National Asthma Education and Prevention Program (NAEPP) for the diagnosis and management of asthma. A retrospective evaluation of medication management of asthma patients with a recent emergency department visit or inpatient hospitalization for an asthma exacerbation is planned.

Public Comment: No public comment.

Board Decision: None needed.

10. New Drug Products Not Added to PDL: *Diane Neal, R.Ph, (MHP)*

- New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. A variety of products released on the market are not in a drug class that is currently managed or are not specifically addressed in the PDL. As approved by the DUR Board, drug products that appear to be illogical

combinations, kits containing non-drug items or very expensive dosage forms where inexpensive alternatives exist are temporarily blocked and brought to the DUR Board on a periodic basis for approval of permanent block or a decision to unblock. The enclosed table highlights drug products blocked from drug files dated 01/04/07 - 08/02/07. DUR Board members were asked to comment if it was felt that a drug product should not be blocked.

Public Comment: No public comment.

Board Decision: None needed.

11. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

12. General Announcements: *Diane Neal, R.Ph, (MHP)*

FDA Safety Alerts

- Thiazolidinedione Drug Class – Heart Failure/Ischemic Risks: The FDA has determined that an updated label with a boxed warning on the risks of heart failure was needed for the entire thiazolidinedione class. There has been much recent controversy surrounding the cardiovascular side effects of Avandia®, including increased risk of heart attacks. The FDA has not made a definitive ruling regarding that particular cardiovascular side effect. It was recommended that there be no PDL or criteria changes at this time.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

- Virasept® in Women and Children: The FDA has recommended that any pregnant women be removed from Virasept® therapy due to a process related impurity. The claims history was reviewed and one patient receiving both Virasept® and a prenatal vitamin was identified and the prescriber notified. The FDA also recommended that children not begin therapy with Virasept® but any current pediatric users could continue. Coding will be put in place to block prescriptions for women of child bearing age and children so that a PA would be required.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

13. Adjourn: Meeting adjourned at 9:35 p.m.

Next DUR Board Meeting
Tuesday, October 9, 2007
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.